United States Senate

Committee on Finance

Washington, D.C. 20510

For Immediate Release
Tuesday, July 24, 2007

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Senators reveal effort by the FDA to suppress scientific dissent and downplay safety concerns

WASHINGTON — Sens. Chuck Grassley and Max Baucus are sounding the alarm about a second senior FDA official who was sidelined after voicing safety concerns about the diabetes drug Avandia, and they are questioning the make-up of an FDA committee assigned to review emerging risks about the drug.

The senators have asked the FDA Commissioner to account for what they've learned through investigative staff interviews of FDA scientists in advance of next week's FDA advisory committee meeting about Avandia.

Baucus and Grassley said they were troubled by reports that the composition of the advisory committee that will conduct this review favors the perspective of the FDA office that approved the drug rather than the FDA office that is responsible for post-market drug surveillance.

"The FDA undermines public safety every time it works to muzzle one of its own scientists. It's time to stop this dangerous and repetitive practice where the FDA tries to shoot the messenger when it doesn't want to hear the message," Grassley said. "It also destroys the checks and balances that ought to be part of the FDA's work to look out for the public interest when FDA leaders give more say and more sway to the office in charge of drug approval than they do to the office in charge of post-market review with questions of drug safety."

"Hardworking and knowledgeable employees at the FDA strive to keep Americans and their health care providers informed about drug safety, but under Commissioner von Eschenbach's leadership it seems that drug manufacturers' interests may be allowed to trump science," said Baucus. "Based on our ongoing investigation, it appears that FDA staff who voiced safety concerns about Avandia were removed from the very jobs that are supposed to protect the American public. The news that FDA will hold an Advisory Committee meeting on July 30th regarding Avandia is a promising development. The FDA must make decisions that are based on science and aim to protect the health of the American public."

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The text of the Grassley-Baucus letter to Commissioner Andrew C. von Eschenbach follows here.

July 23, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

As Chairman and Ranking Member of the United States Committee on Finance (Committee), it is our duty under the Constitution to conduct oversight into the actions of the executive branch, including the activities of the Food and Drug Administration (FDA). The Committee has exclusive jurisdiction over the Medicare and Medicaid programs and a responsibility to ensure that the more than 80 million Americans who receive health care coverage under these programs, and all Americans, receive drugs that are both safe and effective.

We continue to have concerns about FDA's process for ensuring drug safety and we have been closely following FDA's post-marketing activities on the diabetes drug, Avandia. On July 10th, we met with you regarding FDA's handling of post-marketing concerns generally and with Avandia specifically. At that time, we both voiced significant concerns that FDA was not letting science consistently guide decision-making at FDA. You agreed with us that open scientific discussions without fear of reprisal were essential to FDA's executing its mission. On June 4, 2007, Senator Grassley expressed specific concerns regarding FDA's treatment of Dr. Rosemary Johann-Liang, the former Deputy Director of the Division of Drug Risk Evaluation (DDRE) in the Office of Surveillance and Epidemiology (OSE), and urged you to take appropriate corrective actions. USA Today reported that the departure of Dr. Johann-Liang from her position in OSE was in part due to frustration with her job at the FDA. Dr. Johann-Liang had been verbally reprimanded for signing off on a recommendation that a black box label be placed on Avandia for congestive heart failure (CHF). "[T]he agency doesn't want to hear that there are problems," she told USA Today. She went on to say that, "I think in general, there is a culture of 'the drug is always innocent.'"

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Suppression of dissent at the FDA is terribly troubling to both of us. Today, we are writing regarding another FDA employee who was removed from the review of Avandia after voicing safety concerns related to that drug. During a recent interview with Finance Committee staff, a senior medical officer in the Office of New Drugs (OND), who at one point was the primary reviewer for Avandia, told staff investigators that s/he was told to stop participation in the review of potential cardiovascular safety problems associated with Avandia. Since 2005, the senior medical officer believed that there was enough evidence to support a black box warning regarding the risk of CHF.

Interestingly, the senior medical officer's removal from the review happened at the same time that DDRE was recommending stricter labeling for Avandia, in particular a black box warning for CHF. What makes this allegation even more troubling is that numerous FDA employees told our investigators that this senior medical officer had the most experience with the drug class that includes Avandia. In fact, the senior medical officer had been looking at this particular drug class for about 6 years. It is our understanding that s/he was replaced by someone without experience in this drug class. The senior medical officer told our investigators, "It was the first time that this had happened to me, getting pulled off [a drug]." Another employee told our investigators, "OND does not like a black box."

Given our July 10th discussion, this new allegation is especially significant and raises our level of concern about FDA interference in safety decisions regarding Avandia and the joint Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee (Advisory Committee) meeting scheduled for July 30 to discuss the safety of Avandia. We understand that OND has the lead responsibility for the upcoming advisory committee meeting instead of OSE and do not understand the logic behind this decision. The Government Accountability Office (GAO) reported that OSE's role in advisory committee meetings was unclear and that OND generally set the agenda and determined who would present to the Advisory Committee and what issues would be discussed at meetings.

The GAO recommended that FDA clarify OSE's role. Clearly, we share GAO's concerns and have continuously expressed to you our clear sense that OND does not give post-marketing drug safety the attention and priority it deserves. When we met with you on July 10, you told us that you were working to give OSE greater control over drug safety. We would appreciate you keeping us apprised of your progress.

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It also has been reported to us that a majority of the Advisory Committee members are coming from OND consultant pools rather than OSE consultant pools. We have been advised that the FDA personnel who will be sitting at the table with the Advisory Committee members and participating at the meeting break down as follows: two members of OSE to represent the post-marketing perspective and four members of OND to represent the pre-approval perspectives. Given that the focus of this meeting is the safety of Avandia in the post-marketing environment, we find this troubling.

Thank you for your prompt attention to this matter. We expect a response to the concerns set forth in this letter before the July 30, 2007 Advisory Committee meeting.

Sincerely,

Max Baucus
United States Senator
Chairman of the Committee on Finance

Chuck Grassley
United States Senator
Ranking Member of the Committee on Finance

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